

**REMARKS/ARGUMENTS**

Claims 1, 6, 9, and 10 are amended herein.

Applicant's thank Examiner for recognizing that Claims 1 and 5 are novel and not obvious, and thus patentable.

**Claim Rejections 35 U.S.C. § 112****Indefiniteness**

Claims 2, 3, 4, 7, and 8 were rejected as indefinite for lacking antecedent basis for R = H. Claim 1 has been amended to allow R to be hydrogen. This amendment is supported by the rejected claims and the specification (see the structures on p. 9-10, and 12-14). Thus, this rejection is believed to be overcome.

Claims 6 and 10 were rejected as being indefinite because it was not clear whether the depicted structure was the  $\omega$  chain or the entire compound. Applicants have replaced the structure with that of p. 13, which makes the relationship to the  $\omega$  chain with the rest of the molecule clear. The claim has also clarified that the compound is depicted by the structure.

Applicants point out that "adding, removing, or substituting a non-hydrogen atom of the  $\omega$  chain" is fully explained in the specification from p. 13, line 6 to p. 14, line 9. Thus, Applicants believe that the claim is no longer indefinite.

**Enablement**

Claim 9 was rejected as not being enabled. 35 U.S.C. § 112 requires that the patent application "enable any person skilled in the art to which [the claimed invention] pertains, or with which it is most nearly connected, to make and use

the same.” The test for enablement is whether “the experimentation needed to practice the invention [is] undue or unreasonable.” MPEP 2164.01. The claims are drawn to the use of the disclosed compounds in the treatment or prevention of glaucoma or the treatment of ocular hypertension. Thus, enablement requires that a person be able to make the compounds and use them for treatment or prevention of glaucoma or treatment of ocular hypertension without undue or unreasonable experimentation.

If Applicants correctly understand Examiner, Examiner alleges that the claims are not enabled because: 1) the specification does not allow a person of ordinary skill to select a useful dose without undue experimentation, and/or 2) Examiner doubts that the compounds would be useful in treating intraocular pressure.

Selection of a useful dose can be accomplished without undue experimentation. The EC50 value provides a reasonable starting point for the target concentration in the anterior chamber of the eye, which is the target tissue for reducing intraocular pressure. A routine pharmacokinetic study can be used to determine how much drug is required in the dosage form to provide the desired concentration to the eye. Modifications from this starting point to obtain a useful concentration were routine at the time of filing. Furthermore, the dosage/activity relationship of a number of prostaglandins were well known in the art at the time of filing. Thus, finding an effective dose is enabled by the assay provided, the known dosages of related compounds, and the knowledge of routine procedures that were well known in the art.

Applicants provide herewith evidence that the claimed compounds are effective in treating glaucoma. Prostaglandin EP4 agonists are well known to be useful in treating glaucoma. Applicants submit herewith a declaration under Rule 132 showing that a claimed compound is an EP4 agonist. The present claims are relatively narrow in scope, and similar structural changes have been made to

other compounds with similar activity without loss of activity. For example, see U.S. Patent Number 7,179,820. Therefore, the claimed compounds are EP4 agonists, and are effective in treating glaucoma or reducing intraocular pressure.

Since Applicants have shown that a useful dose can be determined without undue experimentation, and that the compounds are useful for the claimed use, the claim is enabled. Therefore, Applicants respectfully request that the rejection be withdrawn.

Examiner also alleges that the claim is not enabled because it claims the “prevention” of glaucoma or ocular hypertension. While Applicants maintain that ocular hypertension may be prevented by the claimed method, Applicants have nevertheless amended the claims to exclude prevention of ocular hypertension.

However, Applicants maintain that the claimed method can prevent glaucoma. Consider the following from Kass (*Arch Ophthalmol.* 2002;120:701-713, enclosed): “[t]opical ocular hypotensive medication was effective in delaying or **preventing** the onset of POAG [primary open angle glaucoma] in individuals with elevated IOP.” It is now generally accepted in the art that reducing intraocular pressure can prevent glaucoma. The presently claimed compounds are prostaglandin EP4 agonists; and prostaglandin EP4 agonists are known to lower intraocular pressure. Therefore, Claim 9 is enabled for the treatment of glaucoma.

On the basis of the amendments and the arguments presented herein, Applicants believe the claims are patentable as they now stand. Therefore, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Please charge Deposit Account 01-0885 for any fees related to this response.

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Respectfully submitted,

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